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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,888	06/29/2001	Tom A. Grigliatti	4810-59380	3346

7590

12/07/2005

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EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/896,888	Applicant(s) GRIGLIATTI ET AL.	
	Examiner Nancy T. Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17,23 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-7, 11-17 and 30 is/are allowed.
- 6) ☒ Claim(s) 8,23 and 27 is/are rejected.
- 7) ☒ Claim(s) 9,10, 28 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3-17, 23 and 27-30 are pending in the case.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on 1/28/98. It is noted, however, that applicant has not filed a certified copy of the Canada 2221819 application as required by 35 U.S.C. 119(b).

Claim Objections

Claim 27 is objected to because of the following informalities: the claim recites "an IE2B element having at least 95% sequence identity to ACAGGACGC (SEQ ID NO:10)". However, since the recited sequence is only 9 nucleotides in length, the alteration of one nucleotide would result in an element having only about 89% sequence identity to SEQ ID NO:10, and therefore, no alterations are possible within the limits of the claim. Therefore, the recitation of 95% sequence identity lacks significance.

Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 29 recites that the insect promoter comprises a sequence having at least 95% sequence identity to SEQ ID NO:1. It is dependent on claim 9, which recites an insect promoter that comprises

the sequence as shown in SEQ ID NO:1 from bp 351 to bp 527. Therefore the dependent claim does not contain every limitation present in the claim on which it depends, and could be infringed by products which do not infringe the base claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 8 is drawn to a shuttle vector comprising an insect promoter which comprises an IE2B element which comprises the sequence shown in SEQ ID NO:10, and claim 27 recites that the IE2B element has at least 95% sequence identity to the sequence shown in SEQ ID NO:10. The specification discloses that the Op ie2 insect promoter comprises six of these IE2B elements, arranged with a second element (termed GATA) in a rather complex structure. However, the specification does not teach other insect promoters which

comprise this element, or teach the way in which such elements should be arranged in existing insect promoters, which are species that encompassed by the claims. The claims are genus claims in terms of insect promoters comprising an IE2B element at any location, in said promoters, including insect promoters to which said element has been added; the claims encompass a broad class of insect promoters having the recited element. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the promoters comprising the recited element, at any location in said promoters, based on the teachings of the specification. While the specification provides general information on the Op ie2 promoter in which the IE2B element naturally occurs, there is no disclosure of where it should be placed in an insect promoter in which it does not naturally occur. There is no structure function analysis of promoters to provide guidance showing where said element would be effective and not destroy function to provide. The specification discloses that a complex upstream region of the Op ie2 gene, which contains several IE2B elements in particular locations, results in a functional promoter (see Fig. 1 and pages 40- 44), but does not disclose a complete description of immediate early insect promoters in which an IE2B element is present, and which maintains function. Therefore, the specification does not describe the claimed shuttle vector comprising any immediate early insect promoter comprising an IE2B element in such full, clear, concise and exact terms so as to indicate that Applicant has possession of the method at the time of filing the present application. Thus, the written description requirement has not been satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "expressing a heterologous insect ion transport peptide hormone", since it is not clear whether it is intended that the phrase refers to the shuttle vector, i.e. a gene which is present thereon and expressed in the cell, or whether it is not encoded on the shuttle vector.

Conclusion

Claims 9, 10, 28 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1, 3-7, 11-17 and 30 are allowed.

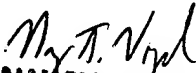
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


NANCY VOGEL, PH.D.
PATENT EXAMINER